

REMARKS

Claims 1-8 were pending. Claims 5, 6 and 8 were withdrawn from consideration by the Examiner as being drawn to a non-elected invention. Claims 1 – 4 and 7 are rejected. Claims 1-4 and 7 is objected to. Claims 1, 2 and 7 have been amended. Claims 5, 6 and 8 have been cancelled. Currently, Claims 1 - 4 and 7 are pending in the present application.

Withdrawn *Streptomyces* sp. Claims 5 and 6, and method of treatment Claim 8 have been cancelled to comply with the Restriction Requirement, without prejudice to pursuing the cancelled subject matter in a divisional application.

Claims 1 and 2 have been amended to add the word "isolated" to the Claims. Claim 2 was further amended to replace the word "recovering" with the word "isolating", and by deleting the phrase "or artificial". Support for adding the word "isolated" is found on page 6, lines 7-33 of the specification.

Claims 1, 2 and 7 have also been amended to replace all occurrences of "I" with "(I)". Claim 2 has also been amended to replace italicized "*sp.*" with non-italicized "sp.".

These amendments do not add new matter to the present application.

CLAIM OBJECTIONS

The Examiner stated that Claims 1, 2 and 7 are objected to because they include reference characters which are not enclosed within parentheses. Claim 2 is also objected to because the font for "sp." in "*Streptomyces* sp." should not be italicized.

Applicants have amended Claims 1, 2 and 7 to replace all occurrences of "I" with "(I)". Applicants have also amended Claim 2 to replace the italicized "*sp.*" with non-italicized "sp.".

In view of the above amendments, Applicants respectfully request that the objection to Claims 1, 2 and 7 be withdrawn.

CLAIM REJECTION UNDER 35 USC 112,

FIRST PARAGRAPH

The Examiner stated that Claims 2-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for a method of preparation of a compound of formula (I) which comprises the cultivation of ATCC #PTA-5316 and ATCC #PTA-5317 or a natural strain of *Streptomyces* sp., does not reasonably provide enablement for a method for the preparation of a compound of formula (I) which comprises the cultivation of any artificial mutant of a *Streptomyces* sp. The Examiner indicated that there is only data present for the production of the compound of formula (I) from MA7327 and MA7331; and there are no working examples in the specification for the preparation of artificial mutants.

Applicants have amended Claim 2 by deleting the phrase "or artificial" and by replacing the term "recovering" with the term "isolating". Support for adding the term "isolating" is found on page 6, lines 7-33 of the specification. Claims 3 and 4 depend from Claim 2 and incorporate the amendments to Claim 2.

In view of the above amendments, Applicants submit that Claims 2, 3 and 4 are enabled. Applicants respectfully request that the rejection of Claims 2, 3 and 4 under 35 USC § 112 first paragraph be withdrawn.

CLAIM REJECTION UNDER 35 USC 101,

FIRST PARAGRAPH

The Examiner stated that Claim 1 is rejected under 35 U.S.C. 101 because the invention is directed to non-statutory subject matter. The Examiner stated that the compound of structural formula (I) is a natural product of the *Streptomyces* sp., and in the absence of the hand of man, e.g. as an isolated product, the natural product is considered non-statutory subject matter.

Applicants have amended Claim 1 by adding the word "isolated" to the Claim. Support for adding the word "isolated" is found on page 6, lines 7-33 of the specification, where the methods for isolating the compound of formula (I) are provided.

In view of the above amendment, Applicants submit that Claim 1 is directed to statutory subject matter. Applicants respectfully request that the rejection of Claim 1 under 35 USC § 101 be withdrawn.

CLAIM REJECTION UNDER 35 USC 102(b),
FOR LACK OF NOVELTY

The Examiner stated that Claims 1-4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by the *Streptomyces platensis* AB3217 taught by Kanbe et al. (PTO-892, Ref W), as evidenced by Singh et al. (PTO-892, Ref X).

The Examiner stated that it is the USPTO's position that the *Streptomyces platensis* strain taught by Kanbe et al. also necessarily produces the instantly claimed compound of formula (I) as the strain taught by Kanbe et al. belongs to the same genus and species as that of the strains taught by Applicants.

Finally, the Examiner stated that it is the USPTO's position that the filtrate would necessarily comprise the claimed compound and suffice as a pharmaceutical composition comprising the instantly claimed compound.

Applicants have amended Claims 1 and 2 to add the word "isolated" before the phrases "compound of structural formula (I)". Claims 3 and 4 depend from Claim 2 and incorporate the amendments to Claim 2.

Applicants submit that Kanbe does not disclose or isolate the compound of structural formula (I) of the present invention. Based on the Kanbe disclosures, it is unclear to one of skill in the art that the compound of formula (I) of the present invention was produced during the fermentation procedure or present in the fermentation media or filtrate disclosed by Kanbe.

Further, Applicants submit that Kanbe does not disclose a pharmaceutical composition of the compound of structural formula (I) of the present invention and a pharmaceutically acceptable carrier. Even if the compound of formula (I) were in Kanbe's filtrate, the filtrate does not comprise a pharmaceutical composition comprising the compound of structural formula (I) and a pharmaceutically acceptable carrier. Kanbe's filtrate is unsuitable as a pharmaceutical composition. The ingredients in Kanbe's filtrate are not pharmaceutically acceptable carriers as required by Claim 7.

Applicants submit that Claim 7 is novel over the disclosures of Kanbe, because Kanbe does not disclose a pharmaceutical composition comprising the compound of structural formula (I) and a pharmaceutically acceptable carrier.

In view of the above amendments, Applicants submit that Claims 1-4 and 7 are novel. Applicants respectfully request that the rejection of Claims 1-4 and 7 under 35 USC § 102(b) be withdrawn.

Applicants believe that all of the rejections and objections have been overcome and therefore earnestly solicit a Notice of Allowance.

Respectfully submitted,

By: /Baerbel R. Brown, Reg. # 47449/
Baerbel R. Brown, Reg. No. 47,449
Patent Attorney for Applicants

MERCK & CO., Inc.
P.O. Box 2000
Rahway, New Jersey 07065
Tel.: (732)594-0672

December 14, 2009